



Italy

The image features a dark navy blue background. On the left, a vertical cream-colored bar is divided into four equal segments by three horizontal teal lines. Two small teal dots are positioned at the intersections of the first and second, and the third and fourth horizontal lines. To the right of this bar, a large teal shape is composed of a trapezoid at the bottom, a rectangle in the middle, and a trapezoid at the top. A thin white vertical line runs down the center of the bottom trapezoid, ending at a small teal circle at its top edge. The word 'Italy' is written in a white, sans-serif font, centered horizontally between the cream bar and the teal shape.

Italy

Understanding the applicable framework

Farindustria's Code dated 14 September 2026 addresses associations, expert patients, services and transparency. Use this edition rather than older translations or misleading website dates (Farindustria, 2026, secs. 4.6, 5.6 bis).

Assess it alongside legislation and organisational tax status. Hospitals, universities and public bodies may introduce separate approvals.

What companies need to understand

RUNTS provides public information and relevant third-sector designations. Not every patient association has the same status or governance (Italian Ministry of Labour and Social Policies, n.d.).

Check legal form, statutes, registration and signing authority. Explain why a particular designation is requested; it is not a universal measure of legitimacy or capacity.

What patient organisations need to understand

The Code requires relevant advance support agreements and addresses non-promotional association services. It establishes specific expert-patient arrangements, including documented expertise and a separate approval route involving non-commercial functions (Farindustria, 2026, sec. 4.6).

Distinguish representatives, people sharing lived experience and expert patients under the Code. Explain the category and evidence needed. Formal training should not be described as a universal condition for valuable patient contribution.

Payment and transparency

The Code addresses remuneration and annual public information for associations and expert patients (Farindustria, 2026, secs. 4.6, 5.6 bis). Explain payee, covered work, expenses and disclosure together.

Agree whether information is independent or commissioned, record editorial authority and include other institutions' approvals in the timetable.

Regulatory and access participation

AIFA Ascolta offers dialogue with associations, networks and federations for information gathering rather than decision-making. Its materials include interests and privacy information (Agenzia Italiana del Farmaco [AIFA], n.d.).

Prepare for the actual opportunity without describing it as an authorisation or reimbursement decision. Preserve the association's control and complete required declarations.

Practical example and local checks

For research-participation advice, distinguish association services and individual expert engagements, document need and confirm approvals. Include preparation and accessibility. Agree expenses, disclosure and confidentiality, and keep later AIFA contributions independent.